K082153

E. 510(K) SUMMARY

NOV 25 2008

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SUBMITTER

Name	**MAJOR Prodotti Dentari S.p.A.**
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Facility registration number	4565
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Document issued on	July 25, 2008

NAME OF DEVICE

Proprietary name	major.repair
Common name	Cold cure polymer for dental prosthesis
Classification name	Denture relining, reparing, or rebasing resin (21 CFR 872.3760, Product Code EBI)
Predicate Devices	Probase Cold by Ivoclar Vivadent AG K913655

DESCRIPTION OF THE DEVICE

Major.repair is a cold-curing polymer for dental prosthesis. For reparing and rebasing dentures. Powder and liquid.

It can be used to:

- repair and rebase prosthesis
- temporary prosthesis

Major.repair is a self-curing polymer composed of a poly-methylmethacrylate powder and a liquid consisting of methylmethacrylate and other ingredients solution.

Major.repair is substantially equivalent to predicate denture base system presently on the USA market and safety and effectiveness are well documented in the dental literature.
All pigments used are approved for alimentary or similar use and are Cadmium free.

Polymerized material technical data (test performed by NIOM Laboratory – Norway) are the following:

- Flexural strength: 66,4 MPa
- Flexural modulus: 2217 MPa
- Water absorption: 21,2 $\mu g/mm^3$
- Water solubility: 1,4 $\mu g/mm^3$
- Residual monomer: 4,0 %

Major.repair is inherently safe when used according to the instructions for use.
It is for use only by dental practitioners; it is not intended for OTC use.

TECHNOLOGICAL CHARACTERISTICS (compared to the predicate device)

Major.repair has the same technological characteristics as the predicate devices since all the devices are complying with ISO 1567:1999 and have:

- Same intended use
- Same polymers composition
- Same working technique

NONCLINICAL TESTING AND CONCLUSIONS

Taking in account that:

- the products and their formulation and use are widely described and totally accepted in dentistry (McKabe, J., Applied Dental Materials, 7th, Blackwell Scientif. Publ.; Phillips, J., Skinner's Science of Dental Materials, Saunders Co.; Graig and Oth., Dental Materials, Properties and Manipulation, 6th, Mosby Publ.; O' Brien, W. J., Dental Materials, Properties and Selection, Quintessence Books);
- a large amount of literature has assessed the clinical liability of these product types and their formulation, dedicating special attention to the denture base products (about 12 articles registered on MedLine last year);
- these product types and their formulation are universal in the last fifty years manufacturing and clinical experience, counting for almost the totality of the not pre-formed temporary crowns and bridges in the world;
- the composition and philosophy of the evaluated products are exactly within what is described in most general literature;
- our company manufactures and sells these products, under similar formulations and processes, since 1966, without any record of human incompatibility or

clinical evidence of adverse effects, having totaled, directly or through connected companies or transferred technologies, more than 200 tons of powders in the last ten years;

we can assess these statements:

- *the materials with which the products are manufactured, own a 50 years history of clinical research, testing and literature, which is largely sufficient not to request any further clinical research or testing;*
- *the products can then be considered clinically tested to be safe;*
- *the clinical monitoring is effected independently by the general literature and it is largely sufficient not to request any further research or testing.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

Ms. Monica Funai
Quality and Regulatory Affairs
MAJOR Prodotti Dentari S.p.A.
Via Luigi Einaudi, 23
I-10024 Moncalieri (Torino)
ITALY

Re: K082153
Trade/Device Name: Major.Repair
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 4, 2008
Received: November 6, 2008

Dear Ms. Funai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K08 2153

Device Name: **major.repair**

Indications for Use: **Major.Repair is a cold-curing polymer for dental prosthesis. Poly-methylmethacrylate based. For reparing and rebasing dentures. Powder and liquid.**

It is used to:

- **repair and rebase prosthesis**
- **temporary prosthesis**

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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